WYETH-AYERST RESEARCH

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U.S. REGULATORY AFFAIRS

October 2, 1998

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, Maryland 20852

RE: Guidance for Industry, "Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug, and Cosmetic Act" <u>Docket No. 98-0265</u>

Dear Sir or Madam:

Wyeth-Ayerst Laboratories, a Division of American Home Products Corporation, respectfully submits comments on the FDA's Guidance for Industry, "Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug, and Cosmetic Act." Wyeth-Ayerst Laboratories is a major research-oriented pharmaceutical company, with leading products in the areas of women's health care, cardiovascular disease therapies, central nervous system drugs, anti-inflammatory agents, vaccines, and generic pharmaceuticals. American Home Products is one of the world's largest research-based pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of prescription drugs and over-the-counter medications.

Section 111 of the FDA Modernization Act (FDAMA) provides for an additional six months of market exclusivity for a product if a sponsor submits certain information relating to use of a drug in the pediatric population. FDA's Guidance for Industry, "Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug, and Cosmetic Act," was issued in response to Section 111 of FDAMA, and contains procedures describing how sponsors may pursue six months of market exclusivity for conducting clinical studies in the pediatric population. Following are comments on the guidance:

There should be explicit provision in the Guidance that completed pediatric study reports may be able to be submitted to FDA up until the day that market exclusivity expires. In such situations, FDA should grant market exclusivity for the period of time it takes to review the study reports for a determination of market exclusivity.

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FDA, in line with recommended procedures stated in the Guidance, has 60 days to review pediatric study data for conformance to the respective written request/written agreement, or 90 days to review the study data for applicability to pediatric exclusivity if a written request or written agreement does not exist. For products which have market exclusivity expiring within the next two-three years, conduct, analysis and reporting of pediatric studies will, in many instances, consume the entire period of time up until the actual date of market exclusivity expiration. In situations where FDA's review of the submitted pediatric study data will extend beyond the market exclusivity expiration date, market exclusivity should be granted for a period not to exceed FDA's review time. This would be a maximum of 60-90 days beyond the date of market exclusivity expiration, dependent on when the pediatric data is submitted with respect to market exclusivity expiration and on the existence of a written request/written agreement for conduct of pediatric studies.

The statement "Studies submitted before FDA issued a Written Request should *not* be used to request pediatric exclusivity" should be stricken from the Guidance.

This statement is found in Section III.C of the Guidance. There is conceivably a situation where a study might be submitted before FDA issues a written request, and the study may satisfy the subsequent criteria of the written request. In this situation, the study should be able to be re-submitted under the pediatric exclusivity provisions of FDAMA.

The Guidance should not require sponsors to notify FDA of any timeframes relevant to conduct and completion of pediatric studies, and should not require sponsors to notify FDA if timeframes for study milestones change.

The Guidance requests that written requests include timeframes for protocol drafting, submission of the protocol to an IND, completion of study enrollment, completion of the study, and drafting and submitting the study report. Further, the Guidance requires sponsors to contact FDA as soon as possible if any of these timeframes might not be able to be met, so that FDA may grant an extension of time.

While the need for FDA to be aware of study milestones in order to properly plan review resources is appreciated, it should be noted that development milestones are often continually and significantly delayed, while target submission dates are usually able to be met. It is a drain on sponsor resources to constantly update the FDA regarding delay of study milestones. It is also a drain on both sponsor and FDA resources to engage in constant liaison regarding agreement of development dates, and it is a drain on FDA resources to reaffirm extension of study milestones in writing. Ultimately, as Congress intended in FDAMA, the sponsor's quest for market exclusivity will drive the completion of pediatric studies prior to market exclusivity expiration. This alone should suffice for a development timeline, and should not need to be modified.

The Guidance should retain the statement that pediatric exclusivity will attach to any exclusivity or patent protection for any drug product containing the active moiety as the drug studied, and for which the party submitting the study(ies) holds the approved NDA.

This statement appears in section X.A. of the Guidance. FDA is commended for its inclusion, as it exemplifies FDAMA incentives for generating pediatric data. Wyeth-Ayerst strongly recommends that the essence of this statement be retained in future revisions of the Guidance, or in any regulations that may supersede the Guidance.

Wyeth-Ayerst Laboratories appreciates the opportunity to comment on FDA's Guidance for Industry, "Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug, and Cosmetic Act." Please contact the undersigned if there are any questions regarding this submission.

Sincerely,

WYETH-AYERST LABORATORIES

Diane Mitrime

Diane Mitrione

Director, Marketed Products I

U.S. Regulatory Affairs

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